UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE DDAVP INDIRECT PURCHASER ANTITRUST LITIGATION	**No. 05 Civ. 2237 (CS)**
	HON. CATHY SEIBEL, U.S.D.J.
THIS DOCUMENT RELATES TO:	**AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**
ALL ACTIONS	
	JURY TRIAL DEMANDED

Indirect Purchaser Plaintiffs ("Plaintiffs"), on behalf of themselves and all others similarly situated, file this Amended Consolidated Class Action Complaint. Plaintiffs, upon personal knowledge as to facts pertaining to themselves, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE CASE

1. This is a nationwide class action alleging violations of federal antitrust law and state antitrust and unfair and deceptive trade practices acts arising from the manufacture and marketing of the brand-name drug DDAVP, an antidiuretic, and its generic equivalents. The generic name for DDAVP is desmopressin acetate.

2. As alleged in greater detail herein, Defendants unlawfully maintained a monopoly in the relevant market by committing fraud and/or inequitable conduct before the United States Patent and Trademark Office ("PTO") in order to obtain U.S. Patent No. 5,407,398 (the "'398 patent") which, in the absence of the fraud, would not have issued. Defendants then improperly listed the fraudulently-obtained patent in the publication of the United States Food and Drug Administration ("FDA") known as the *Orange Book* in order to be able to assert patent infringement claims against,

and block the market entry of, any potential competitor who sought to market a competing generic version of DDAVP. Knowing that the '398 patent was obtained by fraud and/or inequitable conduct, Defendants then initiated patent infringement actions against potential generic competitors, knowing that filing such lawsuits would automatically prohibit the FDA from granting final approval to any of the generic manufacturers for up to 30 months. Finally, Defendants filed a sham citizen petition to further delay market entry of generic competitors.

3. By their unlawful acts, Defendants unreasonably restrained, suppressed and eliminated competition in the market for DDAVP and its generic equivalents, and illegally maintained their monopoly in the market for DDAVP and its generic equivalents. As a result of Defendants' conduct, Plaintiffs and the Class (as defined herein) paid millions of dollars more for DDAVP, at supra-competitive prices, than they would have if competing and/or generic versions of the drug had been available.

4. Plaintiffs in this case are consumers and third-party payors who purchased DDAVP or its generic versions for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries. In Count I of this Complaint, Plaintiffs, on behalf of themselves and all others who are similarly situated, seek equitable and injunctive relief against Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for DDAVP and its generic bioequivalents, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

5. Count II is brought by Plaintiffs on behalf of themselves and those Class members who purchased or paid for DDAVP or its generic equivalents in Arizona, Arkansas, California, Colorado, the District of Columbia, Florida, Hawaii, Idaho, Iowa, Kansas, Maine, Massachusetts,

Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin (the "Indirect Purchaser States"). Count II is brought pursuant to the antitrust and unfair and deceptive trade practices acts of the Indirect Purchaser States.

6. Count III is brought by Plaintiffs on their own behalf and on behalf of the Class, seeking a constructive trust and disgorgement of the property unlawfully obtained by Defendants pursuant to which Defendants have been unjustly enriched.

JURISDICTION AND VENUE

7. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of the federal antitrust laws, particularly Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

8. Plaintiffs also invoke jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interests and costs, and is a class action in which any member of a class of plaintiffs is a citizen of a state different from any defendant.

9. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because Defendants transact business, are found, and/or have agents in this district; because a substantial portion of the affected trade and commerce described below has been carried out in this district; because Defendants brought sham litigation which forms an integral part of these claims in this district; and because other related actions are pending in this district.

RELEVANT MARKETS

10. As to the claims so requiring, the relevant product market is the market for the manufacture and sale of DDAVP tablets and all generic bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States and its territories as a whole (Counts I and III) and the Indirect Purchaser States (Count II). Defendants have monopoly power with respect to DDAVP tablets and its AB-rated generic equivalents.

THE PARTIES

Plaintiffs

Third-Party Payors

11. Plaintiff Vista Healthplan, Inc. ("Vista"), n/k/a Coventry Health Care of Florida, Inc., is a Florida corporation with its principal place of business located in Hollywood, Florida. Vista is a health benefits company that provides comprehensive healthcare benefits to its members, including prescription drug coverage.

12. Plaintiff Pennsylvania Employees Benefit Trust Fund ("PEBTF") is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 150 South 43rd Street, Suite 1, Harrisburg, Pennsylvania 17111-5700. PEBTF provides comprehensive healthcare benefits, including prescription drug coverage, to over 270,000 participants and beneficiaries, which include active and retired employees of the Commonwealth of Pennsylvania and their spouses and dependents. Participants and beneficiaries of the Fund live in Pennsylvania and a number of other states.

13. Plaintiff Painters District Council No. 30 Health and Welfare Fund ("Painters Fund") is located in St. Charles, Illinois and is an "employee welfare benefit plan" and an "employee benefit

plan" within the meaning of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1002(1), 1002(3), 1003(a). As such, the Painters Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). The Painters Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits, including prescription drug coverage, to participants who are employed under various collective bargaining agreements and to their beneficiaries.

14. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund ("PFT Fund") is a voluntary employee benefits plan organized pursuant to Section 501(c) of the Internal Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. The PFT Fund maintains its principal place of business in Philadelphia, Pennsylvania. It provides health benefits, including prescription drug benefits, to approximately 20,000 active participants, and their spouses and dependents who live in Pennsylvania and other states.

15. During the Class Period as described herein, each of the Third-Party Payor Plaintiffs described above has paid supra-competitive prices for DDAVP or its generic equivalents prescribed to one or more of its participants or beneficiaries during the Class Period, and has thereby been injured, and continues to be injured, as a direct and proximate result of Defendants' conduct.

Individual Consumer

16. Helen Seamon is an individual consumer who purchased DDAVP during the Class Period as described herein, and along with other members of the Class, has paid supra-competitive prices for DDAVP or its generic equivalents, other than for resale; has paid more than she would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for DDAVP; and has thereby been injured as a result of Defendants' conduct.

Defendants

17. Defendant Ferring B.V. is a privately held company organized under the laws of the Netherlands.

18. Defendant Ferring Pharmaceuticals, Inc. (hereinafter referred to collectively with Ferring B.V. as "Ferring") is a New York corporation with its principal place of business at 400 Rella Boulevard, Suite 300, Suffern, New York. Ferring Pharmaceuticals, Inc. is a subsidiary of Defendant Ferring B.V.

19. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey. Aventis is the holder of the New Drug Application No. 19-955, for desmopressin acetate tablets, marketed in the United States as DDAVP. Ferring exclusively licensed the right to market and sell DDAVP to Aventis.

INTERSTATE TRADE AND COMMERCE

20. During all or part of the Class Period (defined below), one or more Defendants manufactured and sold substantial amounts of DDAVP in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

21. At all material times, DDAVP manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

22. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of DDAVP.

23. In furtherance of its efforts to monopolize and/or restrain competition in the market for DDAVP and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

24. Defendants' efforts to monopolize and restrain competition in the market for DDAVP alleged herein have substantially affected interstate and foreign commerce.

FACTUAL ALLEGATIONS

A. Brand-Name Drugs vs. Generic Drugs

25. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year, and the cost of drugs dispensed in the United States for the year 2001 was in the range of $160 billion to $170 billion.

26. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

27. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed,

"Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

28. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 90% or more of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

29. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

B. The Federal Scheme For Approval of Brand And Generic Drugs

(i) Branded Drugs And New Drug Applications

30. Under Section 505 of the Federal Food Drug And Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq*., before marketing a new brand drug in the United States, a manufacturer must submit to the FDA a New Drug Application ("NDA"), and the FDA must approve it. 21 U.S.C. § 355(a). The FDA approves an NDA only if it determines that the referenced drug is safe and efficacious for its proposed uses. Once approved, a new drug may be marketed and advertised by the NDA holder only for the use or uses approved by FDA.

31. Among other things, an NDA must contain clinical data and evidence demonstrating that the drug is safe and efficacious for its proposed indications. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50. In addition, the NDA applicant must also submit technical data on the composition of the drug product, including its active ingredient, the means for its manufacture, and a statement of its proposed uses. *Id.*

32. Additionally, an NDA applicant must submit with its NDA certain patent information, including the patent number and the expiration date of any patent that: (1) claims the drug for which the applicant submitted the application; or (2) claims a method of using such drug. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b). For either of these types of patents (*i.e.*, drug composition or method of use), in order to qualify for submission the patents must also be of such a nature that a claim of patent infringement could reasonably be asserted under them if a person not licensed by the owner engaged in the manufacture, use, or sale of the referenced drug. *Id*.

33. As a matter of law, patents that have been obtained by fraud or inequitable conduct by the patent holder cannot lawfully be asserted against a proposed competing manufacturer and thus, by definition, cannot be submitted by the NDA holder to the FDA as part of the NDA submission.

34. Once the FDA approves an NDA, the patent information submitted by the NDA applicant is listed in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" — commonly known as the "*Orange Book*." As brand name drug companies like Ferring and Aventis know, the FDA conducts no independent evaluation of whether a submitted patent qualifies for listing under the statutory or regulatory criteria — instead, the FDA relies entirely on the good faith of the party submitting the patent for listing and accepts as true the drug patent information submitted by the brand-name drug applicant. Indeed, the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . ."). As a result, as numerous courts have recognized, the Agency's role in the patent

listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

35. Moreover, brand name drug companies like Ferring and Aventis also know that the FDA has declined to enact any administrative procedures for resolving patent listing disputes. If a party wishes to dispute a patent listing, it may notify the FDA of its basis for disagreement. 21 C.F.R. § 314.53(f). In response to such a notification, the FDA will simply request the brand-name company to confirm the correctness of the listed patent information. *Id.* Thus, unless the brand-name company *voluntarily* "withdraws or amends its patent information in response to FDA's request, the FDA will not change the patent information in the list." *Id.*

36. As a result of FDA's noninvolvement in reviewing patent submissions, and despite the clear statutory and regulatory limits on the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file, as alleged in more detail below, what are known as "Paragraph IV certifications," which permit the brand-name company to then assert approval-blocking patent litigation against such generic manufacturers. This is because these brand companies, like Ferring and Aventis, know that the FDA does not police this patent listing practice, and that the FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable statute and regulations.

37. This unilateral ability of brand-name companies to cause the listing of patents they know to be invalid or unenforceable in the Orange Book, in contravention of the federal statutes and regulations prescribing which patents qualify for listing, creates an opportunity for unscrupulous brand-name manufacturers, like Ferring and Aventis, to wrongfully thwart a generic competitor from

bringing a lower-priced generic product to market. Tactics like these by such unscrupulous brand-name companies have not gone unnoticed by federal competition authorities. The Chairman of the Federal Trade Commission, for example, in a statement before a Congressional Subcommittee, noted that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade." *Prepared Statement of the FTC Before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives* ("FTC Statement"), at 9 (Oct. 9, 2002). The Chairman also explained that because "the FDA does not review patents presented for listing in the Orange Book . . ., an NDA filer acting in bad faith . . . [has the] power to . . . delay[] generic entry and *potentially cost[] consumers millions, or even billions*, of dollars without valid cause." FTC Statement at 10 (emphasis added). *See also Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 39 (July 2002) ("most of the later-issued patents in the Orange Book raise questions about whether the FDA's patent listing requirements have been met."). *See also* Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 Food Drug Cosm. L.J. 245, 250 (1990) ("Orange Book listing elevates every patent as a potential source of delay to generic competition [and gives] the patentee/NDA holder almost automatic injunctive relief"); Steve Seidenberg, *The Battle Over Drug Patents*, Nat'l L.J. (July 15, 2002), at 1 ("It has become a common — and highly controversial — practice: the world's largest pharmaceutical companies exploiting loopholes in federal drug laws, successfully stifle competition to their blockbuster drugs.").

(ii) Generic Drugs And Abbreviated New Drug Applications

38. In 1984, Congress amended the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355, commonly known as the "Hatch-Waxman Amendments" or simply "Hatch-Waxman." Hatch-Waxman amended the FDCA to, among other things, facilitate and expedite the approval and marketing of generic drugs.

39. In order to bring low-cost generic drugs to the marketplace more quickly, the Hatch-Waxman Amendments established a streamlined procedure whereby generic drug manufacturers could seek approval of generic drugs without having to go through the costly and time consuming process of independently compiling the clinical safety and effectiveness data as did the original NDA holder. This is accomplished through the submission of an Abbreviated New Drug Application ("ANDA"), pursuant to which the generic applicant is permitted to rely upon the brand manufacturer's clinical data and the FDA's previous determination that the brand drug is safe and effective, as long as the ANDA applicant can establish, *inter alia*, that (1) the proposed generic drug has the same active ingredient(s) as the brand drug; (2) the route of administration, dosage form and strength of the proposed generic drug is the same as the brand drug; (3) the proposed generic drug is bioequivalent to the brand drug; and (4) the labeling for the proposed generic drug is the same as the approved labeling for the brand drug. 21 U.S.C. § 355(j); 21 C.F.R § 314.94. Where a generic drug is deemed equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. Generic drugs are considered by the FDA to be in all material respects identical to their brand-name counterparts in terms of their safety and efficacy for the treatment of their approved indications.

40. In enacting Hatch-Waxman, Congress also provided that the proposed generic manufacturer, in compiling an ANDA, may utilize the brand drug in any way that is reasonably related to the preparation and submission of an ANDA free from any claim that such activity infringes any United States patent. 35 U.S.C. § 271(e)(1). At the same time Congress provided this safe harbor to generic applicants allowing them to undertake the development work necessary to compile an ANDA, Congress also sought to protect the *legitimate* rights of patent holders that might be infringed by the marketing of generic versions of their patented product. Accordingly, if the owner of the NDA (*i.e.*, the brand-name manufacturer) has listed a patent or patents in the Orange Book in relation to the approved brand drug, an ANDA filer is required, as part of its ANDA, to file a specified certification with respect to each such listed patent. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R § 314.94(a)(12)(i)(A).

41. Specifically, a generic drugmaker must certify that the brand drug is either: (i) not patented (paragraph I certification); (ii) protected by a patent that has expired (paragraph II certification); (iii) patented, but setting forth the date the patent will expire (paragraph III certification); or (iv) that the brand drug's patent is either invalid or will not be infringed by the proposed generic drug (paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R § 314.94(a)(12)(i)(A)(1)-(4). A paragraph IV certification requires the ANDA applicant to give notice of the filing to both the owner of the patent and to the holder of the NDA for the approved drug. 21 U.S.C. § 355(j)(2)(B)(i)(I); 21 C.F.R § 314.95(a).

42. A generic ANDA applicant must submit one of these required patent certifications even if the listed patent was wrongfully listed in the *Orange Book* by the NDA holder in the first place. Because the FDA does not involve itself in determining the appropriateness or correctness

of a patent listing, even if a generic competitor believes that the patent is improperly listed, it "must" file one of the required certifications, or else its ANDA will be deemed incomplete and not approvable. *See* 21 C.F.R. § 314.94(a)(12)(vii) and § 314.53(f) (even if generic applicant disputes the appropriateness of an Orange Book listing, if the brand name company refuses to remove the patent voluntarily the generic applicant's ANDA "*must*, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.") (emphasis added).

43. Once an ANDA filer submits a paragraph IV certification, the act of filing constitutes a "technical act of infringement," which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder 45 days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

44. The technical act of infringement created under § 271(e)(2), by the filing of a paragraph IV certification, is an artificial construct to create jurisdiction in the courts to entertain the infringement suit prior to the time the generic applicant's product is approved for sale by the FDA. Without the listing of a patent in the Orange Book and the forcing of an ANDA filer to file a paragraph IV certification in response thereto, an NDA holder is precluded from instituting, due to the court's lack of subject matter jurisdiction, preapproval patent litigation against the ANDA filer and invoking the 30-month stay of approval under 21 U.S.C. § 355 (j)(5)(B)(iii).

45. The mere filing of an infringement action in response to a paragraph IV certification, regardless of the action's underlying merit or the underlying patent's validity or enforceability, gives

the brand name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand-name company ever having to establish likelihood of success on the merits, irreparable harm, balance of hardships, or the public good. Indeed, as a practical matter the brand-name company wins the lawsuit simply by filing it, as the company automatically protects its monopoly for up to two and a half years while the infringement action grinds through the court system.

46. An improper *Orange Book* listing also has additional anti-competitive effects because the first generic company to file an ANDA with a paragraph IV certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other subsequent ANDA applicants. 21 U.S.C. 355(j)(5)(B)(iv). This 180-day exclusivity against other generic competitors is awarded to the first paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the paragraph IV certification. Absent an improper *Orange Book* listing, no paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

C. Prescriptions for Brand And Generic Drugs

47. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-related generic version of that pioneer drug which has been approved by the FDA is available.

48. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording

of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

49. Once a physician writes a prescription for a brand-name drug such as DDAVP, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

D. Defendants' Fraudulent Prosecution of the '398 Patent

(i) The Original DDAVP Patents

50. In 1969, the PTO issued Patent No. 3,454,549 (the "'549 Patent") entitled "Desamino-Arginine-Vasopressin" which claimed the compound and process of making a synthetic version of the naturally occurring human hormone vasopressin. The claimed synthetic version replaced the terminal amino group in naturally occurring vasopressin with a hydrogen atom. The resulting claimed invention was a synthetic compound that had three times the antidiuretic effect of naturally occurring vasopressin.

51. In 1970, the PTO issued Patent No. 3,497,491 (the "'491 Patent") entitled "1Deamino-8-d-Arginine Vasopressin" or "DDAVP" which claimed a polypeptide of vasopressin functioning as a targeted antidiuretic for the treatment of diabetes insipidus. Ferring was the exclusive licensee of the '491 patent until its expiration in 1987.

52. In 1977, Ferring received approval from the FDA to market an intranasal formulation of DDAVP as an antidiuretic. Shortly thereafter, Aventis obtained approval to market the same nasal formulation and eventually obtained approval to market an injectable version of DDAVP.

53. It was known in the art that desmopressin acetate could prevent the diuretic symptoms associated with diabetes when absorbed through the walls of the patient's mouth via a dissolving tablet, or through the patient's nasal passage via a liquid spray or plastic tube. Those modes of taking the medication were cumbersome and time-consuming. It would be an improvement if the drug could be administered in a solid oral dosage form, where it would be swallowed and absorbed through the gastrointestinal tract.

54. By 1990, both the '549 Patent and the '491 Patent had expired and the inventions claimed therein had entered the public domain. In anticipation of losing patent exclusivity on the DDAVP compound, Ferring submitted patent application Serial No. 809,937 that would ultimately issue as the '398 patent (the "'398 Patent Application") on December 17, 1985. The '398 Patent Application attempted to patent a form of DDAVP that was gastro-intestinally absorbable, i.e., a tablet form of DDAVP. If successful, the '398 Patent Application would have given Ferring renewed exclusivity in the sale of DDAVP products because Ferring would be the only company allowed to market the tablet form of DDAVP. Because tablet forms of prescription drugs are typically more popular than nasal or injectable versions, and specifically here would be less cumbersome and time-consuming, the '398 Patent Application was a significant business opportunity for Ferring.

(ii) Duty Of Candor and Good Faith in Dealing with the Patent Office

55. Rules governing patent prosecution impose a duty of candor and good faith on those dealing with the PTO, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The Rule provides that:

> Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

56. As explained in more detail below, Ferring knowingly provided false and misleading information to the PTO in order to overcome the PTO's legitimate rejection of Ferring's attempt to claim an invention that was plainly anticipated by the previous DDAVP patents. With an intent to mislead the PTO, Ferring submitted declarations from ostensibly independent experts during the '398 patent prosecution when, in fact, those experts were at all relevant times undisclosed consultants to Ferring. Had Ferring not knowingly violated its duty of candor and good faith in dealing with the PTO, the '398 patent would not have issued.

(iii) Ferring's Wrongful Conduct in Obtaining the '398 Patent

57. The two inventors listed on the '398 Patent Application were Dr. Hans Vilhardt, a former research director at Ferring; and Mr. Helmer Hagstam, who was then the technical director at Ferring. The inventors assigned their rights in the application to Ferring.

58. After submitting the '398 Patent Application on December 17, 1985, Dr. Vilhardt and his attorney appeared at a preliminary interview with PTO Examiners on May 28, 1986, during

which they discussed the '398 Patent Application and prior art. In particular, they discussed the '491 Patent and the '549 Patent.

59. The PTO examiners noted that the '491 patent had taught that, for antidiuretic purposes, desmopressin acetate could be used "for the parenteral, peroral, intranasal, subcutaneous, intramuscular, or intravenous application." The examiners were concerned that the disclosure of a "peroral" application in the '491 patent suggested oral administration of the drug for gastrointestinal absorption.

60. Vilhardt argued to the examiner that the term "peroral" as used in the '491 patent did not teach oral administration for gastrointestinal absorption, but absorption through the walls of the mouth. The examiner suggested that applicants obtain evidence from a "non-inventor" which would support Vilhardt's interpretation of the term "peroral."

61. On June 12, 1986, Ferring submitted a preliminary amendment, which added three new claims, and also submitted four declarations in support of issuing the '398 patent. Of the four declarations, Dr. Vilhardt submitted two, Dr. Czernichow submitted one and Dr. Miller submitted one. Each of these declarations was submitted with CV's attached. Dr. Czernichow's and Dr. Miller's declarations asserted that one skilled in the art who read the '491 Patent describing peroral administration in connection with DDAVP would conclude that the term "peroral" referred to administration through the mouth for absorption through the cheek or under the tongue, and not to oral administration for gastrointestinal absorption. The CV of Dr. Czernichow did not disclose any relationship with Ferring or interest in the '398 Patent Application, although Dr. Vilhardt did disclose such interest.

62. On November 20, 1986, the PTO rejected the '398 Patent Application as anticipated by, or obvious, in light of the '491 Patent.

63. On May 20, 1987, Ferring filed a request for reconsideration, arguing that the '491 Patent did not expressly, impliedly or inherently teach the claims of the '398 Patent Application. Ferring submitted several articles relating to the subject matter in support of its position that those skilled in the art would not find the '398 patent obvious in light of the '491 Patent.

64. On August 14, 1987, the PTO again rejected the '398 Patent Application as anticipated by, or obvious, in light of the '491 Patent.

65. Ferring appealed the PTO decision on November 13, 1987. Ferring's brief included a copy of Dr. Czernichow's declaration, again not disclosing any relationship with Ferring or interest in the '398 Patent Application.

66. On September 21, 1990, the Board of Patent Appeals and Interferences affirmed the examiner's rejection of the '398 patent, concluding that the "peroral" recitation in the '491 Patent coupled with the knowledge of the prior art, disclosed in a 1974 publication by I. Vavra and others, is suggestive of and anticipated the oral administration of DDAVP for gastrointestinal absorption in humans. The Vavra study involved the administration of desmopressin to rats by stomach gavage and showed that DDAVP caused antidiuresis in rats.

67. After review of the Board's decision rejecting the claims, Dr. Vilhardt wrote to the patent attorney that "everything now depends on our ability to deal with the Vavra paper." In preparing to "deal" with the Vavra paper, Vilhardt contacted at least two Ferring consultants regarding additional declaration evidence: Dr. Iain Robinson and Professor Barth. Both Robinson and Barth signed declarations in support of Vilhardt's positions. In addition, at some point during

the '398 prosecution, Dr. Vilhardt also sought declarations from two other Ferring consultants, Professor Leonard Share and Professor Besser.

68. On November 21, 1990, Ferring responded to the rejection by the Board of Patent Appeals by filing an amendment after appeal. Along with the amendment, Ferring filed five declarations submitted by Dr. Vilhardt, Dr. Miller, Dr. Czernichow, Dr. Robinson and Dr. Barth.

69. On April 8, 1991, the PTO issued a Notice of Allowability, allowing the '398 patent which issued on September 10, 1991. The invention disclosed and claimed in the '398 patent is an orally effective form of desmopressin designed to be absorbed by the body through the gastrointestinal tract.

(iv) Unbeknownst to the PTO, Drs. Czernichow, Barth, and Robinson Were Paid Consultants of Ferring

70. Unbeknownst to the PTO, Drs. Czernichow, Barth, and Robinson, all of whom submitted crucial "non-inventor" declarations in support of the '398 Patent Application, were paid consultants of Ferring. Dr. Czernichow submitted a declaration in 1986, and Drs. Czemichow, Barth and Robinson each submitted declarations in 1990, after the Board of Patent Appeals affirmed the examiner's earlier rejections.

71. The first Czernichow declaration was dated June 4, 1986, and was in direct response to the examiner's request for non-inventor declarations regarding the meaning of "peroral." In it, he states that the '491 Patent did not teach him, and opined that it would not teach others skilled in this art, to administer DDAVP in oral dosage form for gastrointestinal absorption by humans. He further declared that the meaning of "peroral" administration in the '491 Patent meant that DDAVP could be administered through the mouth for sublingual or buccal absorption. Dr. Czernichow's

second declaration was submitted in 1990, and addressed the Vavra reference by the Board of Patent Appeals.

72. Dr. Czemichow's CV does not mention any affiliation with Ferring, but he was a Ferring consultant and received research funding from Ferring from 1985 to 1986, and again from about 1988 to 1990, the same time period during which he submitted his declarations in support of the '398 Patent Application.

73. Dr. Iain Robinson, a neuroendocrinologist, filed a declaration in support of the '398 patent in November of 1990, which specifically addressed the Vavra reference by the Board of Patent Appeals after Ferring's appeal of the rejection. Dr. Robinson had been employed as a pre-clinical research director at Ferring from 1985-1986, and during his tenure as research director, Ferring sponsored Dr. Vilhardt's research on the effects of DDAVP. Drs. Robinson and Vilhardt were also friends and in regular contact during this time. Robinson was also a paid Ferring consultant for some months before his job as research director in 1985, and was again a paid Ferring consultant from 1986-1989. After he left Ferring, the company sponsored a research program in his laboratory for about three years.

74. Dr. Barth, a Professor of Organic Chemistry and Biochemistry, also submitted a declaration in support of the '398 patent in 1990, which specifically addressed the Vavra reference. Dr. Barth worked on several paid research projects for Ferring as a paid consultant.

75. Vilhardt communicated with each declarant before their declarations were submitted to the PTO. Vilhardt also provided "draft declarations" to Barth and Robinson for use in drafting their submissions to the PTO.

76. With intent to mislead the PTO, Ferring knowingly provided the false and misleading declarations to the PTO in order to overcome the PTO's legitimate rejection of the '398 Patent Application. The fact that the PTO rejected the '398 Patent Application three times before receiving the false and misleading declarations indicates that but for Ferring's fraud, the '398 patent would not have issued. At all relevant times, Defendants understood that the '398 patent was procured by fraud and was therefore invalid and not capable of being properly listed in the *Orange Book* or enforced against a third-party seeking to manufacture DDAVP.

(v) Defendants cause the '398 patent to be listed in the *Orange Book*

77. Despite knowing that the '398 patent was procured by fraud, Defendants caused the '398 patent to be listed in the *Orange Book* in connection with Defendants' NDA pending before the FDA. It was wrongful and unlawful to list the '398 patent in the *Orange Book* because, as Defendants knew, there was no reasonable basis to believe that the '398 patent was valid or that a claim of patent infringement could reasonably be asserted on the basis of that patent due to Ferring's fraud and/or inequitable conduct.

78. As a result of Defendants wrongfully listing the '398 patent in the *Orange Book*, no generic manufacturer could submit an ANDA seeking approval to market a generic version of DDAVP in the United States without certifying either that its product would not be marketed in the United States until the expiration of each listed patent (Paragraph III certification) or that each listed patent was invalid or not infringed by the proposed product (Paragraph IV certification).

79. If the '398 patent had not issued, Defendants would not have been able to list it in the Orange Book, nor would Defendants have been able to file lawsuits against generic competitors, as alleged in more detail below, invoking the 30-month Hatch-Waxman stay of FDA approval of an

ANDA. Furthermore, absent the fraudulent Orange Book listing, no generic would have filed a paragraph IV certification, and therefore, no generic company would have received an 180-day exclusivity to sell its product.

80. On September 6, 1995, the FDA approved Defendants' NDA. Defendants began selling DDAVP soon after the NDA's approval. Sales of DDAVP tablets were approximately $78 million in 2000, $98 million in 2001, $125 million in 2002, $157 million in 2003 and $180 million in 2004.

81. In the absence of the fraudulently-obtained '398 patent, other pharmaceutical companies would have sought and obtained FDA approval for their own versions of desmopressin tablets without having to undertake the burden and expense of investigating the '398 patent and being sued for patent infringement.

82. In the absence of the fraudulently-obtained '398 patent, one or more other pharmaceutical companies would have launched competing tablet desmopressin products. By obtaining the '398 patent through fraud and/or inequitable conduct, Defendants unlawfully eliminated this avenue of competition.

(vi) Defendants File Sham Litigation Against Barr Laboratories

83. Barr Laboratories ("Barr") submitted ANDA No. 76-470 to obtain FDA approval to engage in the commercial manufacture, use and sale of generic desmopressin acetate oral tablets prior to the expiration of the '398 patent. Barr's ANDA contained a Paragraph IV Certification that the '398 patent was invalid and/or unenforceable.

84. Barr sent Ferring and Aventis letters dated October 29, 2002, notifying each that Barr's ANDA was received by the FDA, and that Barr's ANDA contained a Paragraph 1V Certification.

85. On December 13, 2002, Ferring and Aventis filed a timely suit in the United States District Court for the Southern District of New York, asserting that Barr infringed the '398 patent. Barr asserted counterclaims for patent invalidity and non-infringement. *Ferring B.V. v. Barr Laboratories, Inc.*, No. 02 Civ. 9851(CLB) (S.D.N.Y.). Defendants, with full knowledge that the '398 patent had been procured by fraud and was unenforceable, proceeded with the baseless patent infringement litigation in order to invoke the 30-month Hatch-Waxman stay. This conduct had the effect of preventing generic versions of DDAVP from coming to market and consequently of illegally extending Defendants' monopoly on DDAVP while the litigation progressed.

86. Barr sought discovery relating to the prosecution of the '398 patent. This discovery ultimately revealed that the declarations presented to the PTO following its request for objective, non-inventor testimony were in fact provided by Ferring consultants.

87. On February 7, 2005, the district court granted summary judgment to Barr, holding that Ferring had committed inequitable conduct by deliberately deceiving the PTO about the "non-inventor" declarations submitted with the '398 Patent Application. The Court found "clear and convincing evidence of an intent to mislead the examiners," and that "the deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative." The Court found further that the "close and undisclosed long-standing associations between the declarants in this case and Ferring and Vilhardt should have been disclosed in order to avoid the foreseeable inference of fraud that logically arises from the undisputed facts of this case."

88. On the key issue of "but for" causation, the District Court found the following:

> Defendant contends, and this Court agrees, that the PTO must have relied substantially on these declarations, as there is no alternative explanation offered for the Board's final allowance of the claims after several prior rejections by the PTO.

89. The Court stated "that three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent's issuance speaks loudly as to motive and intent." The Court concluded the "totality of the circumstances in this case reveals that no genuine issues of material fact as to inequitable conduct remain so as to preclude summary judgment," and found "the patent unenforceable on that ground."

90. Ferring took a timely appeal to the United States Court of Appeals for the Federal Circuit. On February 15, 2006, the Federal Circuit affirmed the District Court on the ground that the patent is unenforceable due to inequitable conduct. *See Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

91. For example, with respect to materiality, the Federal Circuit stated, in part, that:

> Despite appellants' assertions that the identity of the declarants was completely irrelevant to the examiners, the actual record made on summary judgment demonstrates otherwise. Indeed, it shows that the background, at least of the declarants Robinson and Czernichow, *was not only material but was highly material*. The examiners specifically requested "non-inventor" affidavits. Moreover, the examiners expressly stated that they were concerned about the objectivity of those trying to distinguish the '491 patent from the '398 patent. In their 1986 rejection, the examiners stated: "As Applicants are the exclusive licensee of the Zaoral ['491] patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the patent referred only to sublingual or buccal routes, whereas the instant mode of administration [in their new patent] excludes such routes as it involves absorption by the gastrointestinal tract." The examiners were thus keenly aware of the fact that Ferring was the exclusive licensee of the '491 patent, which was soon to expire, and had an interest in convincing the PTO that the application described an invention not disclosed in the '491 patent. The examiners treated Ferring and the applicants as one and the same. Based on the examiners' request for non-inventor affidavits and their

> subsequent comments, it is clear from the summary judgment record that the examiners were concerned about the objectivity of those providing declarations and their relationship to Ferring, and that they communicated this concern to the applicants.
>
> Under such circumstances, the applicant is on notice as to the materiality of information regarding the declarants' ties to Ferring. . . .

437 F.3d at 1181 (emphasis added; citation to record omitted).

92. The Federal Circuit also found ample evidence of intent to deceive in the summary judgment record, stating, in part, as follows:

> First, Barr established that Vilhardt knew of significant past relationships of at least two of the declarants. Vilhardt was aware that Robinson was Ferring's pre-clinical research director while Vilhardt was serving as a consultant to Ferring researching the very peptide at issue. Robinson served as Vilhardt's contact at Ferring during this time. Vilhardt was also aware of Bath's affiliation with Ferring. Although he testified that he did not believe that Barth was a Ferring "consultant," he indicated that he was aware of a working arrangement between Ferring and Barth's employer under which Ferring had funded support for Barth's research. Additionally, as Ferring notes in its brief, "[b]etween 1988 and 2000, [Barth] worked a month most years in Dr. Vilhardt's laboratory for which he was paid a maintenance stipend."
>
> As to the second question – Vilhardt's knowledge of the materiality of the information – it is undisputed that the examiners were concerned about the identity of the affiants and that Vilhardt was aware of this concern since he was present at the interview with the examiners when the concern was expressed. . . . [T]he fact that the examiners here requested "non-inventor" affidavits and expressed concern about bias supports the district court's conclusion that Vilhardt was on notice that disinterested affidavits were necessary, and knew or should have known that the Ferring affiliations were material.
>
> Finally, the appellants urge that there is potentially a credible explanation here for the withholding. The crux of appellants' argument is that there are possible benign explanations for the withholding and that evidence might have been developed at trial to support those theories. Thus, appellants assert that it was improper for the district court to grant summary judgment to Barr "without seeing or hearing from the accused Dr. Vilhardt," and complained that "Barr's counsel did not ask Dr. Vilhardt or any other declarant a single question which would bear on the issue of intent." We find this argument to be quite remarkable. On summary judgment, in order to create a genuine issue, the appellants bore the burden of

> submitting an affidavit from Vilhardt to contradict the movant's evidence of intent if they believed that testimony from Vilhardt would establish credible evidence for the withholding. Appellants cannot create a genuine issue by suggesting that Vilhardt *might* have proffered favorable evidence at trial.

437 F.3d at 1191-92 (footnotes and references to record omitted; emphasis in original). The Federal Circuit held that "there is evidence in the summary judgment record that supporting a conclusion that the past relationships were deliberately concealed." 437 F.3d at 1193.

93. Based upon the summary judgment record, construed in the light most favorable to Ferring and Aventis, the Federal Circuit agreed that summary judgment was appropriate. 437 F.3d at 1194 ("In all of the above circumstances, we cannot find that the district court abused its discretion in finding inequitable conduct.").

94. Defendants' litigation against Barr was objectively baseless and was brought solely for the anticompetitive purpose of delaying generic competition.

95. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Defendants' sham litigation, the FDA would have focused more attention on Barr's ANDA and would have granted approval earlier than July 1, 2005.

96. In addition, the sham litigation forced Barr to divert resources away from the FDA approval process and towards defending itself against Defendants' claims of patent infringement. Once Defendants filed the infringement action, Barr had little practical incentive to pursue even conditional approval because the approval would have been meaningless in the absence of a favorable court ruling on infringement or validity.

97. Thus, by suing Barr, Defendants delayed FDA approval of generic desmopressin acetate tablets by: (1) provoking a slow track on the FDA's consideration of Barr's ANDA; and/or (2) undermining Barr's vigorous pursuit of its ANDA.

(vii) Defendants File Sham Litigation Against Teva Pharmaceuticals

98. Teva Pharmaceuticals USA, Inc. ("Teva") also submitted an ANDA application to the FDA to sell a generic version of desmopressin acetate tablets.

99. On or about June 9, 2004, Ferring received notice that Teva had filed an ANDA with a paragraph IV certification seeking to market a generic version of desmopressin acetate tables.

100. On July 20, 2004, Defendants filed a patent infringement action against Teva in the United States District Court for the District of Delaware. As with the Barr litigation, Defendants commenced and maintained this lawsuit even though it was: (1) objectively baseless, in that no reasonable litigant could ultimately expect success on the merits given Defendants' fraud and/or inequitable conduct on the PTO; and (2) motivated by a desire to delay a potential competitor knowing all the while that the lawsuit was a sham.

101. By suing Teva, Defendants delayed FDA approval of generic desmopressin acetate tablets by: (1) provoking a slow track of the FDA's consideration of Teva's ANDA; and (2) undermining Teva's vigorous pursuit of its ANDA.

(viii) Defendant Ferring Files A Sham Citizen Petition With the FDA

102. On February 2, 2004, during the same time in which Defendants were prosecuting their baseless patent infringement lawsuit against Barr, Ferring knowingly filed a sham citizen petition with the FDA to further delay generic entry.

103. The filing of a citizen petition with the FDA pursuant to 21 C.F.R. §§ 10.20 and 10.30 is the process by which a person requests "the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action."

104. Ferring's citizen petition requested that the FDA establish what Ferring knew were unwarranted bioequivalence requirements for proposed generic formulations of DDAVP. Ferring asked the FDA to mandate that all ANDAs, like Barr's, seeking approval to market a generic version of DDAVP include more stringent evidentiary proofs of bioequivalence, including comparative clinical end-point studies in children, and separate evidence of bioequivalence for each dose level.

105. In support of its petition, Ferring asserted that conventional bioequivalence testing for DDAVP would not provide adequate information about intra-subject variability with respect to the rate, extent, and duration of subject absorption, and would not adequately account for the potential impact of an individual's age and development. Ferring further asserted that because DDAVP is the first and only oral peptide approved by the FDA, and because it is primarily indicated for use in enuretic children, unique bioequivalence criteria must be established for generic approval.

106. Ferring's requests were designed to create an insurmountable regulatory barrier to generic entry, as the required clinical studies and evidentiary proof would be scientifically unnecessary, unreasonably expensive and unnecessarily time-consuming.

107. These and other arguments made in Ferring's petition had no basis in science or fact, and were asserted in bad faith, merely as another prong of its strategy to block generic competition.

108. For example, Ferring was incorrect both from a regulatory standpoint and as a factual matter in its assertion that because DDAVP is administered in microgram doses, has low oral

absorption, has a low effective plasma concentration and may be difficult to assay, a traditional pharmacokinetic study is insufficient to establish bioequivalence. Those problems simply do not exist, as Ferring knew.

109. Ferring also could not begin to convincingly explain why clinical studies in children are necessary to establish bioequivalence for a generic DDAVP formulation. Ferring did not even attempt to articulate a scientifically substantiated reason as to why a generic DDAVP product shown to be bioequivalent to DDAVP in healthy adults would not be bioequivalent in the approved pediatric population.

110. With respect to Ferring's request that bioequivalence be established for each dose level, Ferring presented no data to support its assertion that a multiple-dose study requirement would more appropriately address bioequivalence concerns for DDAVP.

111. More troubling still, Ferring also purposely failed to address or even acknowledge all of the relevant authorities on bioequivalence. Notably, Ferring's petition failed to disclose or describe a published study conducted by Aventis, the sponsor of the DDAVP NDA, that reached conclusions flatly inconsistent with Ferring's own position. In fact, Ferring did not cite any studies unfavorable to its own arguments, which is itself violative of 21 C.F.R. § 10.30(b)'s requirement that petition signatories "attest that to the best of their knowledge and belief, the petition includes representative data and information known to the petitioner that are unfavorable to the petition."

112. Ferring's petition was frivolous as a matter of law in multiple respects. Ferring's reliance on sections 320.32 and 320.33 of the Code of Federal Regulations was entirely baseless. Section 320.32, by its own terms, applies only to "a product not subject to section 505(j) of the act." 21 C.F.R. § 320.32 (2005). ANDAs for generic DDAVP plainly fall under section 505(j). Similarly,

section 320.33, which sets forth criteria to assess whether a drug has a known or potential bioequivalence problem, has no applicability to an ANDA for generic DDAVP. 21 C.F.R. § 320.33 (2005).

113. In light of the obvious and overwhelming scientific, factual, and legal shortcomings of its petition, Ferring could not reasonably have believed that its petition would be well received by the FDA, much less that its requested relief would be granted.

114. Ferring did not care that its petition was frivolous, because it knew that the mere filing of the petition, no matter how baseless, would serve to preserve its DDAVP monopoly. Indeed, while Ferring along with Aventis had already used a fraudulently obtained patent to delay generic market entry, Ferring apparently did not intend to fight a single-front battle. Instead, Ferring sought to elicit the FDA's assistance with its generic blocking strategy.

115. On July 1, 2005, the FDA denied Ferring's citizen petition in its entirety, concluding that Ferring offered "no convincing evidence (i.e., data or other information)" why the FDA should depart from its long-established and well-settled methodologies to establish bioequivalence, and noting that Ferring had failed to cite to FDA the Aventis study which was flatly inconsistent with the position advanced by Ferring.

116. Ferring's citizen petition was objectively baseless, was filed with the knowledge and interest that its mere filing would delay FDA's approval of a competing generic product, regardless of its underlying lack of merit, with the sole anticompetitive purpose of delaying generic competition. In other words, Ferring's filing of the citizen petition amounted to unfair, deceptive and unconscionable conduct.

117. On the same day that the FDA denied Ferring's citizen petition, the FDA granted final approval of Barr's ANDA for generic desmopressin tablets. Absent Ferring's sham citizen petition, the FDA would have approved Barr's ANDA at an earlier date.

118. On July 15, 2005, Barr launched its generic DDAVP product. Because Barr was the first ANDA filed to challenge Defendants' patent, it received a 180-day exclusivity period. Thus, as a result of Defendants' anticompetitive conduct, no other generic manufacturers could enter the market until Barr's exclusivity period had run.

119. On January 25, 2006, after Barr's exclusivity period ended, the FDA approved Teva's ANDA, and Teva began selling its generic DDAVP tablets soon thereafter.

EFFECTS ON COMPETITION

120. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell DDAVP without being subject to generic competition. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP products much sooner.

121. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, end-payors, such as Plaintiffs, would have been free to substitute a lower-priced generic for the higher-priced brand name drug and consequently would have paid substantially less for DDAVP.

122. By preventing generic competitors from entering the market, Defendants injured Plaintiffs by causing them to pay more for DDAVP or its generic equivalent than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to preserve.

123. As a result of Defendants' anticompetitive conduct, Plaintiffs and the Class were compelled to pay artificially inflated prices for DDAVP tablets and were deprived of the opportunity to purchase lower-priced generic versions of DDAVP tablets

CLASS ACTION ALLEGATIONS

124. Plaintiffs bring this action on behalf of themselves and as representatives of a Class defined as follows:

> All persons or entities throughout the United States and its territories who purchased and/or paid for DDAVP or generic versions of DDAVP for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class") during the period from February 25, 2001, through the date on which the anticompetitve effects of Defendants' conduct cease ("the Class Period"). For purposes of the Class definition, persons and entities "purchased" DDAVP if they paid some or all of the purchase price.

Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); and all persons or entities that purchased DDAVP for purposes of resale, or directly from any of the Defendants or their affiliates.

125. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to the equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

126. Although Plaintiffs do not know the exact number of Class members, they believe it to be, at a minimum, in the tens of thousands. DDAVP had annual U.S. sales of approximately $121 million for the twelve months ending October 2002. Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and

records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations.

127. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because Defendants have acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate equitable and injunctive relief with respect to the Class as a whole. Such conduct includes Defendants' exclusionary and anticompetitive efforts to mislead the PTO, the filing of a bogus patent in the *Orange Book*, the filing of baseless litigation, and the filing of the sham citizen petition.

128. Questions of law and fact common to the Class include:

(a) whether the '398 patent described herein was obtained through fraud or inequitable conduct;

(b) whether Defendants' litigation asserting infringement of its patents described herein was baseless;

(c) whether Defendants' actions illegally maintained its monopoly power;

(d) whether Defendants engaged in sham litigation for the purpose of preventing competition;

(e) whether Defendants have monopolized and attempted to monopolize the market for DDAVP and generic bio-equivalents to DDAVP;

(f) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for DDAVP and generic bio-equivalents to DDAVP;

(g) whether Plaintiffs and members of the Class are entitled to equitable and/or injunctive relief; and

(h) whether Plaintiffs and the Class have been damaged and the aggregate amount of damages.

129. Plaintiffs' claims are typical of the members of the Class, in that Plaintiffs purchased and/or paid for DDAVP throughout the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of DDAVP. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

130. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs are not antagonistic to those of the Class. In addition, Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

131. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

132. Plaintiffs know of no difficulty to be encountered by litigation of this action that would preclude its maintenance as a class action.

COUNT I

(FOR INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT)

133. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

134. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to improperly obtain and extend their monopoly power in the Relevant Markets. This course of conduct included, *inter alia*, the following acts: (i) the intentional submission of fraudulent statements to, and omissions of material facts from, the PTO; (ii) the intentional submission of false patent information to the FDA by listing the '398 patent in the *Orange Book*; (iii) the prosecution of baseless, sham patent litigation against a potential generic manufacturer; and (iv) the filing of a sham citizen petition. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly.

135. Defendants' infringement action against Barr constituted sham litigation, in that the suit was objectively baseless due to, *inter alia*, the presence of the prior art and the inequitable conduct which rendered the '398 patent unenforceable; and in that Defendants' motivation in bringing the actions was to directly interfere with the ability of any generic manufacturers to market less expensive generic versions of DDAVP that would compete with the brand-name product.

136. Defendants intentionally and wrongfully created and maintained monopoly power in the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

137. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of

being deprived of the ability to purchase less expensive, generic versions of DDAVP, and paying higher prices for such products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury the antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

138. Plaintiffs and the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II

(FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES)

139. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

140. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as unfair, deceptive and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, in a continuous and uninterrupted flow of intrastate and interstate commerce throughout the United States, as well as in each Indirect Purchaser State, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. Arkansas: The aforementioned practices by Defendants were and are in violation of the Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-107, *et seq*.

c. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

d. Colorado: The aforementioned practices by Defendants were and are in violation of the Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-105, *et seq*.

e. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

f. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq.*;

g. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statute § 480-2; the claim under this statute is expressly limited to unfair and deceptive acts outlined above;

h. Idaho: The aforementioned practices by Defendants were and are in violation of Idaho's Consumer Protection Act, Idaho Code §§ 48-601, *et seq*.

i. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

j. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq*.

k. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

l. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Massachusetts; Defendants' conduct further substantially affected commerce within Massachusetts because thousands of class members paid substantially higher prices for DDAVP within Massachusetts, thus injuring class members within Massachusetts;

m. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Michigan; Defendants' conduct further substantially affected commerce within Michigan because thousands of class members paid substantially higher prices for DDAVP within Michigan, thus injuring class members within Michigan;

n. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.,* and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

o. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Mississippi; Defendants' conduct further substantially affected commerce within Mississippi because thousands of class

members paid substantially higher prices for DDAVP within Mississippi, thus injuring class members within Mississippi;

p. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

q. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Nevada; Defendants' conduct further substantially affected commerce within Nevada because thousands of class members, many of them elderly, paid substantially higher prices for DDAVP within Nevada, thus injuring class members within Nevada;

r. New Hampshire: The aforementioned practices by Defendants were and are in violation of New Hampshire's Antitrust Statute, N.H.Rev. Stat. § 356:11, *et seq*., and New Hampshire's Consumer Protection Act, N.H.Rev.Stat. § 358-A:2, *et seq*.

s. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq*.;

t. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq*., and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq*.

u. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

v. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq*.;

w. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.,* and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq*.;

x. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Tennessee; Defendants' conduct further substantially affected commerce within Tennessee because thousands of class members paid substantially higher prices for DDAVP within Tennessee, thus injuring class members within Tennessee;

y. Utah: The aforementioned practices of Defendants were and are in violation the Utah Trade Practices Act, Utah Code §§ 13-5-1, *et seq*., the Utah Consumer Sales Practices Act, Utah Code §§ 13-11-1, *et seq*.

z. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

aa. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in West Virginia; Defendants' conduct

further substantially affected commerce within West Virginia because thousands of class members paid substantially higher prices for DDAVP within West Virginia, thus injuring class members within West Virginia; and

bb. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*; Moreover, Defendants' conduct maintained artificially high prices for DDAVP in Wisconsin; Defendants' conduct further substantially affected commerce within Wisconsin because thousands of class members paid substantially higher prices for DDAVP within Wisconsin, thus injuring class members within Wisconsin.

141. As a result of the conduct described above, Plaintiffs and the Class have sustained substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of DDAVP in their home state, and paying prices for such products that were higher than they would have been but for Defendants' unlawful actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

142. Defendants' conduct caused pharmacies in every state to charge higher prices for DDAVP as a result of the lack of competition by AB-rated generic versions of DDAVP, including transactions that occurred purely intrastate. Sales of DDAVP at supracompetitive prices did occur in each state and the effects of the anticompetitive conduct were experienced in every state.

143. To the extent that Plaintiffs are aware of any state's statutory requirement to notify a state's attorney general of the filing of this complaint, such notice has been executed.

144. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to the aforesaid statutes.

COUNT III

(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS)

145. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

146. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts include improperly listing their patent in the *Orange Book*; submitting fraudulent misrepresentations to, and concealing material facts from, the PTO; filing a sham citizen petition; and filing and pursuing two baseless patent infringement actions. Specifically, Defendants have been unjustly enriched, to the detriment of Plaintiffs and the Class by the receipt of, at a minimum, unlawfully inflated prices and illegal monopoly profits on their sale of DDAVP**.**

147. Defendants have benefitted from their unlawful acts, and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for DDAVP made by Plaintiffs and the Class.

148. Plaintiffs bring this claim under the laws of the 50 states and the District of Columbia.

149. Plaintiffs and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs and the

Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

(a) The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiffs as the representatives of the Class;

(b) The Court declare the conduct alleged herein to be in violation of Section 2 of the Sherman Act, of the laws of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(c) Plaintiffs and the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

(d) Plaintiffs and the Class recover the amounts by which Defendants have been unjustly enriched;

(e) Defendants be enjoined from continuing the illegal activities alleged herein;

(f) Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

(g) Plaintiffs and the Class be granted such other and further relief as the Court deems just and necessary.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Respectfully submitted,

Dated: July 26, 2011

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished on this 26th day of July, 2011 via e-mail and U.S. Mail to: Barbara Wootton, Esquire, Arnold & Porter LLP, 555 Twelfth Street, NW, Washington, DC 20004; and Julie E. McEvoy, Esquire, Jones Day, 51 Louisiana Avenue, N.W., Washington, DC 20001.

s/ Kevin B. Love
Kevin Love